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Review

Efficacy of clinical gait analysis: A systematic review

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ABSTRACT

The aim of this systematic review was to evaluate and summarize the current evidence base related to the clinical efficacy of gait analysis. A literature review was conducted to identify references related to human gait analysis published between January 2000 and September 2009 plus relevant older references. The references were assessed independently by four reviewers using a hierarchical model of efficacy adapted for gait analysis, and final scores were agreed upon by at least three of the four reviewers. 1528 references were identified relating to human instrumented gait analysis. Of these, 116 original articles addressed technical accuracy efficacy, 89 addressed diagnostic accuracy efficacy, 11 addressed diagnostic thinking and treatment efficacy, seven addressed patient outcomes efficacy, and one addressed societal efficacy, with some of the articles addressing multiple levels of efficacy. This body of literature provides strong evidence for the technical, diagnostic accuracy, diagnostic thinking and treatment efficacy of gait analysis. The existing evidence also indicates efficacy at the higher levels of patient outcomes and societal cost-effectiveness, but this evidence is more sparse and does not include any randomized controlled trials. Thus, the current evidence supports the clinical efficacy of gait analysis, particularly at the lower levels of efficacy, but additional research is needed to strengthen the evidence base at the higher levels of efficacy.

1. Introduction

The appropriate role of gait analysis in clinical care remains controversial. Proponents argue that gait analysis provides important information needed to optimize the care of patients with complex walking problems [1]. Opponents counter that, although gait analysis is a useful tool for research, as a clinical tool it adds unnecessary cost without providing any proven benefits to individual patients [2]. Consequently, the utilization of gait analysis is highly variable [3]. Whether or not gait analysis is used is largely determined by individual physician preference, availability of motion analysis services, and insurance coverage, which is also highly variable. The uneven utilization and reimbursement are at least partially due to differences in interpreting the evidence related to the efficacy of clinical gait analysis.

Evaluating the clinical impact of a diagnostic test is complex because diagnostic tests have an indirect effect on patient outcomes [4,5]. By influencing the treatment decision-making process, gait analysis may affect patient management and, consequently, patient outcomes. Fryback and Thornbury have proposed a widely used framework for evaluating the efficacy of a diagnostic test [4,5]. This framework organizes evidence of efficacy into a hierarchy of levels ranging from technical data acquisition to treatment decision-making to patient and societal outcomes. This framework was first used to evaluate magnetic resonance imaging, but can also apply to diagnostic tests in general [6,7]. It is widely used in medical technology assessments such as those conducted by the United States (U.S.) Agency for Healthcare Research and Quality (AHRQ) Technology Assessment Program, which provides information contributing to coverage decisions by the U.S. Centers for Medicare and Medicaid Services and insurance carriers [6,7]. In this review, we utilize this framework to evaluate clinical gait analysis.

The aim of this systematic review was to evaluate and summarize the current evidence base related to the clinical efficacy of gait analysis. As noted above, the review was performed using the established framework developed by Fryback and Thornbury [4,5]. Evidence of efficacy is needed by patients,

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families, healthcare providers, insurers and policy makers to better determine and agree on the appropriate clinical use of gait analysis. It is also important to establish the current evidence base to understand what evidence exists and what additional research is needed.

2. Methods

A literature review was conducted to identify references related to human gait analysis published between January 2000 and September 2009. We limited our search to Medline/PubMed databases as these contain most of the reports on instrumented gait analysis. We next identified search terms using MEDLINE thesaurus online and Medical Subject Headings (MeSH). Our search terms included gait, locomotion, walking, biomechanics, kinematics, and electromyography combined with the terms analysis, evaluation, and diagnostic techniques. We also used the combined terms of gait analysis, motion analysis, and biomechanic analysis. The articles identified by the search were screened to determine whether they were related to gait analysis in humans; references not related to human gait analysis ($N = 83$) were excluded. Additional older references known to the reviewers were also included. The search was limited to English language references.

The Fryback and Thornbury framework for technology assessment was adapted for application to gait analysis (Table 1). The levels of efficacy were (1) technical efficacy, (2) diagnostic accuracy efficacy, (3 and 4) diagnostic thinking and treatment efficacy, (5) patient outcomes efficacy, and (6) societal efficacy. A score of 7 was added for studies that used gait analysis as a descriptive or outcome measure, but did not provide information related to efficacy. Technical efficacy refers to the physical process of obtaining data, including the accuracy and reliability of the equipment used and the procedures employed in data collection (e.g., marker placement, anthropometric measurements, model used to analyze data, processing methods used to obtain kinematics, kinetics, and temporospatial parameters). Diagnostic accuracy efficacy refers to interpretation of the data collected, including performance in classifying patients and making diagnoses, interpreting data for individual patients (e.g., through pattern recognition or automatic or semi-automatic interpretation), and identifying measures predictive of good or bad outcomes for specific treatments. Diagnostic thinking and treatment efficacy refers to the impact of gait analysis on treatment decision-making and the treatment actually done (change in treatment or reinforcement of treatment plan). This category combines the Fryback and Thornbury levels 3 (diagnostic thinking) and 4 (therapeutic) because they are tightly coupled in gait analysis. Patient outcomes efficacy refers to the effect on outcomes for individual patients. Societal efficacy reflects cost effectiveness or cost-benefit analysis from a societal viewpoint (e.g., savings to health care system, more efficient use of resources, etc.).

Using this framework, all identified references were initially scored independently by two of four reviewers. Reviewers were allowed to assign multiple scores to references that addressed multiple levels of efficacy. References identified as addressing efficacy by at least one of the reviewers (scores 1–6) were then also scored by the remaining two reviewers. After the initial scoring, the review criteria were discussed and clarified using 12 references with discrepant scores to focus the discussion. All references with discrepant scores were then independently re-evaluated by the individual reviewers; discussion and re-scoring was performed iteratively until agreement was achieved among at least three of the four reviewers. The final scores were those agreed upon by at least three of the four reviewers.

3. Results

1528 references were identified relating to human instrumented gait analysis. Of these, 240 were identified by the first two reviewers as addressing efficacy levels (scores 1–6) and appropriate for additional review. The majority of the excluded references ($N = 1063$) used gait analysis as an outcome or descriptive measure only, e.g., using gait kinematics to evaluate the outcome of a surgery without evaluating the efficacy of the gait analysis itself. Other excluded references were not focused on classic instrumented clinical gait analysis ($N = 142$).

Based on the scores of all four reviewers, 105 original articles addressed technical efficacy, 78 addressed diagnostic accuracy efficacy, eight addressed diagnostic thinking and treatment efficacy, four addressed patient outcomes efficacy, and one addressed societal efficacy. An additional 22 original articles addressed multiple levels of efficacy (Fig. 1). Of 18 review articles, five addressed technical efficacy, four addressed diagnostic accuracy efficacy, two addressed diagnostic thinking and treatment efficacy, and seven addressed multiple levels of efficacy.

3.1. Technical accuracy (level 1)

Over half of the studies relating to efficacy addressed technical accuracy ($N = 116$ original articles). These included direct assessments of accuracy and reliability, as well as the development of methods to improve the quality of the data collected.

3.2. Diagnostic accuracy (level 2)

The next largest group of studies addressed diagnostic accuracy ($N = 89$ original articles). These studies evaluated the efficacy of gait analysis in classifying patients into diagnostic groups or identifying measures to select treatments or predict outcomes. Studies developing methods to improve the usefulness of the data interpretation were also included.

3.3. Diagnostic thinking and treatment efficacy (levels 3–4)

11 original articles evaluated the impact of gait analysis on clinical decision-making and treatment. The results consistently showed that treatment plans change after consideration of gait analysis data and that the treatment ultimately performed differs from the plan before gait analysis. Specifically, treatment plans with and without gait analysis differed in a high percentage of patients (52–89%) and procedures (40–51%) [8–13]. In addition, 37–39% of the procedures planned before gait analysis were not ultimately done, and 28–40% of the procedures actually done were not planned before gait analysis [11,13]. Gait analysis recommendations were followed in a high percentage of cases, with 92–93% of recommendations for specific surgical procedures being followed [13,14] and 77% of patients having an exact match between the surgeries recommended by gait analysis and the surgeries ultimately performed [14]. This suggests that the changes in treatment are at least partly due to the addition of gait analysis. The specific articles pertaining to efficacy levels 3–4 and above are listed in Table 2.

3.4. Patient outcome efficacy (level 5)

Seven original articles evaluated the effect of gait analysis on patient outcomes (Table 2). All of these studies used case-control or case series designs; none were randomized controlled trials. These studies compared outcomes among groups of patients

Table 1
Scoring scheme based on hierarchical model of efficacy [5] adapted for gait analysis.

Score	Efficacy type	Description
1	Technical	Physical process of obtaining data (system and personnel)
2	Diagnostic accuracy	Effectiveness of data plus interpretation of data
3–4	Diagnostic thinking and treatment	Effect on decision-making and treatment
5	Patient outcome	Effect on outcomes for individual patient
6	Societal	Cost-effectiveness or cost-benefit from societal viewpoint
7	–	Gait analysis as a descriptive or outcome measure